Risk factors for fracture mobility six weeks after initiation of brace treatment of mid-diaphyseal humeral fractures

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Abstract: BACKGROUND: Recent studies have identified specific subsets of diaphyseal humeral fractures for which functional bracing is less effective. The present study tested the hypothesis that a gap between fracture fragments may be a risk factor (after accounting for other potential risk factors) for fracture instability six weeks after functional bracing of humeral shaft fractures. METHODS: We retrospectively identified seventy-nine adult patients (forty-six men, thirty-three women; forty-two fractures on the right side, thirty-seven fractures on the left), each with an acute, closed, AO type-A2 (oblique, 30°) or type-A3 (transverse, lt;30°) mid-diaphyseal humeral shaft fracture treated nonoperatively at three different level-I trauma centers from June 2004 to August 2011. The gap between the fracture fragments was measured on the first radiographs made after the affected upper extremity was placed in a brace. RESULTS: Sixty-three patients (80%) had documented healing of the fracture. Sixteen patients (20%) had motion at the fracture site and a persistent fracture line shown on radiographs six weeks or more after injury. In multivariable analysis, each millimeter of gap between the main fragments with the patient wearing the brace (odds ratio [OR] = 1.4, 95% confidence interval [CI] = 1.1 to 1.7), smoking (OR = 5.8, 95% CI = 1.4 to 25), and female sex (OR = 5.3, 95% CI = 1.2 to 23) increased the risk of fracture instability six weeks after injury (R2 = 0.38, area under the receiver operating characteristic [ROC] curve = 0.81). CONCLUSIONS: The magnitude of the gap between the fracture fragments is an independent risk factor for fracture instability and the lack of a bridging callus six weeks after a diaphyseal humeral fracture. LEVEL OF EVIDENCE: Prognostic Level IV. See Instructions for Authors for a complete description of levels of evidence.

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Risk Factors for Fracture Mobility Six Weeks After Initiation of Brace Treatment of Mid-Diaphyseal Humeral Fractures

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Background: Recent studies have identified specific subsets of diaphyseal humeral fractures for which functional bracing is less effective. The present study tested the hypothesis that a gap between fracture fragments may be a risk factor (after accounting for other potential risk factors) for fracture instability six weeks after functional bracing of humeral shaft fractures.

Methods: We retrospectively identified seventy-nine adult patients (forty-six men, thirty-three women; forty-two fractures on the right side, thirty-seven fractures on the left), each with an acute, closed, AO type-A2 (oblique, ≥30°) or type-A3 (transverse, <30°) mid-diaphyseal humeral shaft fracture treated nonoperatively at three different level-I trauma centers from June 2004 to August 2011. The gap between the fracture fragments was measured on the first radiographs made after the affected upper extremity was placed in a brace.

Results: Sixty-three patients (80%) had documented healing of the fracture. Sixteen patients (20%) had motion at the fracture site and a persistent fracture line shown on radiographs six weeks or more after injury. In multivariable analysis, each millimeter of gap between the main fragments with the patient wearing the brace (odds ratio [OR] = 1.4, 95% confidence interval [CI] = 1.1 to 1.7), smoking (OR = 5.8, 95% CI = 1.4 to 25), and female sex (OR = 5.3, 95% CI = 1.2 to 23) increased the risk of fracture instability six weeks after injury (R^2 = 0.38, area under the receiver operating characteristic [ROC] curve = 0.81).

Conclusions: The magnitude of the gap between the fracture fragments is an independent risk factor for fracture instability and the lack of a bridging callus six weeks after a diaphyseal humeral fracture.

Level of Evidence: Prognostic Level IV. See Instructions for Authors for a complete description of levels of evidence.

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Nonoperative treatment of diaphyseal humeral fractures is associated with a reported union rate of 92% to 98%, and angular deformity and shortening are well tolerated[1-5]. In contrast, nonunion is disabling because of pain and instability[6-9]. In prior studies, risk factors for nonunion were found to be open fractures, transverse mid-diaphyseal fractures (AO type A3), and spiral fractures (AO type A1) in the proximal part of the shaft[1,10-13]. Sarmiento et al.[1] observed a persistent gap between the fracture fragments in seven of sixteen patients with a nonunion after functional bracing of a humeral shaft fracture but did not quantify the risk of nonunion associated with a fracture gap. Koch et al.[14] mentioned diastasis (and axial deformity) of the fracture ends as an indication for operative treatment. We also have had the clinical impression that a gap between the two main fragments increases the risk for failure of closed treatment. The current study tested the null hypothesis that a gap between the two fragments is not associated with the failure of nonoperative humeral shaft fracture treatment when other potential risk factors for nonunion are accounted for.

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TABLE I Patient Overview

Parameter	Total (N = 79)	Fracture Apparently Healed (N = 63)	Fracture Unstable After 6 Weeks (N = 16)	P Value
Sex*				0.06
Female	33 (42)	23 (37)	10 (63)	
Male	46 (58)	40 (63)	6 (38)	
Age† *(yr)*	48 ± 19 (18-91)	47 ± 19 (18-91)	54 ± 19 (21-85)	0.21
Comorbidities other than diabetes and osteoporosis*	45 (57)	34 (54)	11 (69)	0.29
Smoking*	19 (24)	11 (17)	8 (50)	0.018
Diabetes*	11 (14)	8 (13)	3 (19)	0.69
Osteoporosis*	10 (13)	6 (10)	4 (25)	0.11
Side*				0.16
Left	37 (47)	32 (51)	5 (31)	
Right	42 (53)	31 (49)	11 (69)	
AO type*				0.78
12-A2 (oblique)	27 (34)	22 (35)	5 (31)	
12-A3 (transverse)	52 (66)	41 (65)	11 (69)	
Radial nerve palsy*	6 (8)	6 (10)	0 (0)	0.34
Concomitant injuries*	15 (19)	14 (22)	1 (6)	0.28
Measurement in emergency room†				
Translation *(mm)*	12 ± 6.5 (0-30)	11 ± 5.9 (2-26)	12 ± 8.7 (0-30)	0.85
Gap *(mm)*	2.3 ± 3.1 (0-13)	1.9 ± 2.8 (0-12)	3.8 ± 4.0 (0-13)	0.03
Angulation *(deg)*	24 ± 17 (0-90)	22 ± 16 (0-85)	29 ± 21 (3-90)	0.20
First measurement in brace†				
Time after injury *(days)*	18 ± 11 (0-56)	19 ± 11 (2-56)	14 ± 8 (0-27)	0.097
Translation *(mm)*	10 ± 5.7 (0-26)	10 ± 5.3 (1-26)	10 ± 7.3 (0-25)	0.83
Gap *(mm)*	3.6 ± 3.4 (0-15)	3.0 ± 2.8 (0-11)	6.3 ± 4.5 (0-15)	0.011
Angulation *(deg)*	17 ± 8.9 (2-49)	16 ± 7.8 (2-49)	21 ± 11 (3-40)	0.14
Duration of follow-up† *(days)*	287 ± 303 (61-1588)	210 ± 211 (61-1216)	287 ± 303 (112-1588)	0.002

*The values are given as the number of patients, with the percentages in parentheses. †The values are given as the mean and standard deviation, with the range in parentheses.

Materials and Methods

Patient Selection

Using a protocol with institutional review board approval, we used a prospectively collected trauma database to retrospectively identify 639 consecutive adult patients (age eighteen years or older) in whom an acute, traumatic humeral shaft fracture had been treated at one of three different level-I trauma centers from June 2004 to August 2011. The inclusion criteria were (1) a closed fracture, (2) an AO type-A2 (oblique, ≥30°) or type-A3 (transverse, <30°) fracture, (3) a fracture in the middle third of the diaphysis, (4) no periprosthetic or peri-implant (nail or plate) fracture, (5) nonoperative treatment, and (6) either documented union (clinically and radiographically) two months or more after injury or a recommendation for surgery based on persistent motion between the fracture fragments and a persistent fracture line found on radiographs obtained six weeks or more after injury[13].

Of the eighty-two patients who fulfilled the inclusion criteria, three were excluded because they had had surgical treatment within three weeks after injury. Two of the three requested surgery because of discomfort in the brace, and one patient had surgery because the surgeon thought that there was too much displacement.

The final cohort included seventy-nine patients (forty-six men, thirty-three women; Table I). Forty-two fractures were on the right side and thirty-seven fractures, on the left. The fracture resulted from a fall from a standing height in twenty-one patients, from a fall from a greater height in eight, from a fall not further specified in twenty-two, from a motor-vehicle collision in twenty, and from another mechanism (direct blow, arm wrestling, sports-related) in eight. Radial nerve palsy was present in six patients (8%). Other fractures were present in fifteen patients (19%), including six ipsilateral, nonoperatively treated upper-extremity fractures (hand, distal part of the radius, olecranon, clavicle); three contralateral, operatively treated upper-extremity fractures (humerus, olecranon, distal part of the forearm); five fractures at other sites (pelvis, femur, tibia plateau, tibia shaft, and ankle); and isolated rib fractures in one patient. The patients were followed for a mean of ten months (range, two to fifty-three months).

Treatment Strategy

Orthopaedic trauma surgeons from three hospitals were involved in the treatment of the patients. A coaptation splint, and in some cases a functional brace, was applied in the emergency department. In all cases, a functional brace was applied within two weeks after injury. Alignment was checked on the first radiographs made with the patient wearing the brace, at an average of eighteen days (range, zero to fifty-six days) after the injury. Early post-injury radiographs

TABLE II Predictors of Fracture Instability Six Weeks or More After Injury*

Parameter	P Value	OR	95% CI Lower	95% CI Upper
Smoking	0.017	5.8	1.4	25
Female sex	0.024	5.3	1.2	23
Gap in brace (per mm)	0.003	1.4	1.1	1.7

*R^2 = 0.383, 87.1% correct; area under receiver operating characteristic curve (ROC) = 0.81 (95% CI, 0.66 to 0.96); Hosmer-Lemeshow test = 0.15.

after application of the brace were not made for five patients. Patients wore the brace for six to twelve weeks, depending on when radiographic and clinical signs of union were found. The surgeons' recommendation to proceed with surgery was based on fracture mobility and the absence of radiographic evidence of union six weeks or more after injury. Fracture mobility was assessed with elevation of the shoulder and direct manipulation of the arm.

Data Collection and Definitions

The following data were recorded (Table I): sex, age, comorbidities (smoking, diabetes, known osteoporosis, and other comorbidities such as hypertension, coronary artery disease, and known alcohol abuse), trauma mechanism, AO type (12-A2 or 12-A3), radial nerve palsy, concomitant injuries, union (a patient discharged from care with an apparently healed fracture), duration of follow-up, and recommendation for surgery based on fracture instability and no radiographic signs of union more than six weeks after injury.

Radiographic Measurements

The worst angulation (in degrees), translation (in millimeters), and gap (in millimeters) were measured both on available radiographs made in the emergency department and on the first radiographs made with the patient wearing the brace. The gap was measured as the distance between two lines, one line connecting the edges of the proximal fracture plane and the other (parallel) line drawn along the nearest part of the distal fracture plane (Fig. 1). For the five patients who did not have early post-injury radiographs made with the upper extremity in the brace, we used the radiographs made in the emergency department. Independent, experienced orthopaedic surgeons obtained the radiographic measurements in an unblinded fashion with use of the Aquarius iNtuition workstation (version 4.4.6; TeraRecon, Foster City, California) at one institution and with use of the Centricity software (GE Healthcare; Little Chalfont, Buckinghamshire, United Kingdom) at the other two institutions.

Statistical Analysis

The continuous data are presented as the mean and standard deviation (SD) and range if applicable. The categorical data are presented in absolute numbers and percentages. In bivariate analysis, the chi-square test was used to compare the categorical variables, and the unpaired t test was used to compare the continuous variables. All variables with a p value <0.10 were entered into a binary logistic regression with use of the backward conditional method in order to assess the factors associated with fracture mobility more than six weeks after injury while accounting for confounders.

A post-hoc power analysis determined that forty-four patients would provide 80% power to detect a significant difference (p = 0.05) in the gap found in patients successfully treated with a brace compared with the gap in patients for whom brace treatment was unsuccessful.

Source of Funding

No funding was received in direct support of this study.

Results

Sixty-three patients (80%) had documented healing of the fracture (Table I). There was no significant difference in the average fracture gap between low-energy and high-energy injuries either in the emergency room (p = 0.58) or on the early post-injury radiographs made with the upper extremity in the brace (p = 0.37). All six radial nerve palsies resolved. Sixteen patients (20%) had motion at the fracture site and a lack of bridging callus shown on radiographs made six weeks or more after injury (Fig. 2). The mean interval between the injury and the decision to proceed with surgery was four months (range, two to eleven months). Twelve patients (including six smokers) had an atrophic or oligotrophic mobile fracture, and four (two smokers) had a hypertrophic mobile fracture. In nine patients the fracture healed after one surgical procedure and in three patients, after two. Three patients (all with an atrophic or oligotrophic ununited fracture) declined surgery, and one patient with a hypertrophic nonunion had not had surgery by the time of writing because of medical issues. All four of these patients were followed for more than eight months.

In bivariate analysis, a gap (measured in millimeters) between the main fragments (p = 0.011) and smoking (p = 0.018) were significantly associated with failure of brace treatment, and patient sex (p = 0.06) met the criterion for entry into the multivariable analysis (Table I). Translation and angulation were

Fig. 1

The gap was measured as the distance between two lines, one line connecting the edges of the proximal fracture plane and the other (parallel) line drawn along the nearest part of the distal fracture plane.

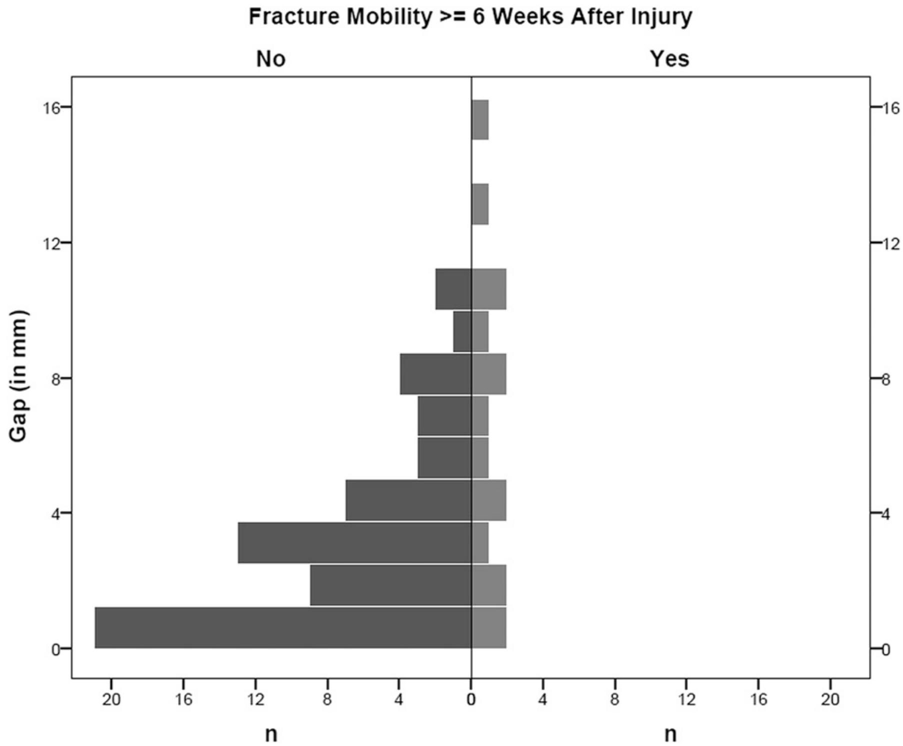

Fig. 2
The number of patients (n) with successful (left) and unsuccessful (right) treatment as a function of the gap in millimeters between the two main fragments.

not associated with fracture instability. In multivariable analysis, a gap between the main fragments while the arm was in the brace, smoking, and female sex were significant risk factors for fracture mobility six weeks or more after injury. Each millimeter of gap increased the risk of failure of closed treatment by about 40% (odds ratio [OR] = 1.4); smoking increased the risk six times; and being female, five times (Table II). The model explained 38% of the variance in successful/unsuccessful treatment and correctly classified 87% of the fractures (R^2 = 0.38, area under the receiver operating characteristic [ROC] curve = 0.81).

Discussion

Functional bracing is a common treatment for closed fractures of the humeral shaft. Most fractures heal, but proximal oblique fractures are at greater risk for nonunion. A fracture gap is a suspected risk factor for nonunion that has not been well studied. Sixteen (20%) of seventy-nine patients with a mid-diaphyseal transverse or short oblique fracture treated with functional brace immobilization had operative treatment or were advised to have surgery for a mobile fracture that did not show radiographic signs of union more than six weeks after injury. The gap (measured in millimeters) on the first radiographs made after the brace was applied, smoking, and female sex were independent predictors for fracture mobility six weeks after injury.

One strength of this study is that we included a large number of patients with a relatively uncommon fracture pattern. Nevertheless, this study should be interpreted in light of its limitations. First, it is a retrospective study based on the medical records from three different institutions. We were not able to evaluate all medical comorbidities (e.g., obesity and alcohol abuse[15,16]) or the exact duration of functional bracing because of the limitations of the documentation. Second, we used the best initial radiographs, five of which were made prior to splint application and therefore might have differed in important ways from the radiographs obtained with the injured extremity in the splint. We acknowledge the inconsistencies in this approach, and we planned the study with the understanding that there are many difficulties with using nonstandardized radiographs in trauma series. Third, it is possible that some of the fractures that were considered healed were hypertrophic nonunions. It is also possible that some of the hypertrophic mobile fractures might have healed without surgery. However, there is a growing consensus that humeral shaft fractures that are mobile more than six weeks after injury will not heal[17]. Fourth, the mean duration of follow-up is rather short, but it is sufficient to determine healing as defined by Sarmiento et al.[1]. A diagnosis of union more than two months after injury would be optimal, but it is unlikely that any stable fractures with radiographic evidence of bridging callus more than two months after injury were eventually diagnosed as nonunions.

Historically, approximately 2% to 5% of all humeral shaft fractures treated nonoperatively have failed to heal[1-3,10,17,18]. We documented a 20% rate of healing problems in midshaft AO type-A2 and type-A3 fractures, which is consistent with studies that showed that AO type-A fractures had the worst union rate (82%) and type C, the best (nearly 100%)[12,19]. Studies of mid-diaphyseal fractures have consistently shown transverse fractures (AO type A3) to be at the greatest risk for nonunion[1,10,14,19,20].

Each millimeter of gap increased the risk of fracture mobility six weeks after injury by about 40%, perhaps because of the larger gap for the callus to bridge, but a larger gap might also reflect greater soft-tissue injury. Smoking increased the risk of fracture instability six weeks after injury nearly six times[21]. We do not have an explanation for why the multivariable model demonstrated that women were five times more likely than men to have fracture instability six or more weeks after fracture. This finding might be spurious, or it might reflect important differences between the sexes.

In summary, our findings suggest that patients with a transverse or short oblique fracture of the midpart of the humeral shaft are at increased risk for fracture mobility six weeks after injury, and the risk correlates with the size of the gap between fracture fragments and with whether the patient smokes. Patients should stop smoking to increase the chance of healing. The results of surgery for delayed union or for nonunion of a diaphyseal fracture of the humerus are comparable with those of surgery performed immediately after the injury, so our preferred strategy is to recommend placement of a functional brace initially and to then offer surgery if the fracture remains mobile six weeks later. ■

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